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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,735	11/05/2001	Joanne Paquin	6670/0K001	5231

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EXAMINER
JARVIS, WILLIAM R A

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/021,735	Applicant(s) PAQUIN ET AL.	
	Examiner William R. Jarvis	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 05 November 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-24 of copending Application No. 10/012,730. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim the use of the combination of pyruvate, an antioxidant, and a lipid for the treatment of neuronal oxidative stress and related conditions. Although the copending application additionally requires ceruloplasmin, the claims of the present invention are nevertheless made obvious thereby, since the claims of the present invention employ the open claim language "comprising," which permits for the inclusion of additional active ingredients (e.g. ceruloplasmin).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating oxidative stress-related conditions, does not reasonably provide enablement for treatment of any type of condition in neuronal cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Since applicant's disclosure only clearly supports treatment of conditions relating to claims 18 and 19, claim 17 should limited thereto.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's submitted Martin journal article (document 5 cited on Form PTO-1449) in view of Izumi et al (document 1). The Martin reference teaches the use of the combination of pyruvate, an antioxidant, and lipids for reducing cellular injury from oxygen radicals and the healing of

wounds. See the abstract and the section beginning on the second column, last paragraph on page 158. Applicant's claims differ in that they treating a neuronal oxidative stress-related condition including brain trauma, neurodegenerative diseases, poisoning of neuronal cells, ALS, preserving neuronal grafts, and for the diminution of drug side effects. However, the secondary reference teaches the use of pyruvate for the treatment of neuronal degeneration associated with ischemia, hypoxia, hypoglycemia, or cellular disorders which interfere with the energy metabolism of neurons; see the abstract and the claims.

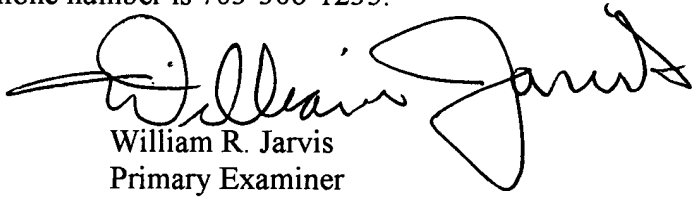
In view of the facts that pyruvate is known to be effective at reducing neuronal degeneration and providing a neuroprotective effect, that antioxidants are well-known in the art to reduce damage caused by free radicals, and that the combination of pyruvate, antioxidants, and certain lipids are synergistically effective at reducing injury from oxygen radicals, one skilled in the pharmaceutical arts would have been motivated to treat a neuronal oxidative stress-related condition with an antioxidative composition comprising pyruvate, an antioxidant, and at least one lipid. To treat specific oxidative stress-related condition including brain trauma, neurodegenerative diseases, poisoning of neuronal cells, ALS, preserving neuronal grafts, and for the diminution of drug side effects is obvious since it is well-known to the skilled artisan that antioxidant compositions are effective at treating various types of conditions involving oxidative damage. The claimed amounts of active ingredients are obvious since it is within the skill of the pharmaceutical artisan to determine the amount or dosage of a drug that provides the therapeutic effect most effective for treating the patient's condition while minimizing adverse side effects. To employ additional agents such as metal chelators and excipients in the composition is obvious since they are conventionally employed in the art to improve the stability of the composition.

8. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Martin journal article discussed *supra*. Since the composition comprising the combination of pyruvate, antioxidant, and lipid is clearly taught by Martin for therapeutic use, one skilled in the pharmaceutical arts would have been motivated to make a liquid composition (e.g. for parenteral administration) by simply mixing the active ingredients with a buffered saline solution, which are conventionally employed in the pharmaceutical arts, in order to obtain a solution or fine suspension. The additional step of centrifuging or filtering the solution is a well-known step employed for the purpose of purifying a composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



William R. Jarvis
Primary Examiner
Art Unit 1614

wrj
February 9, 2003